

DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs

- Doramectin

Authorised

Product identification

Medicine name:

DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs

DECTOMAX 10 MG/ML SOLUTION INJECTABLE POUR BOVINS OVINS ET PORCINS

Active substance:

- Doramectin

Target species:

- Sheep
- Pig
- Cattle

Route of administration:

- Intramuscular use
- Subcutaneous use

Product details

Active substance and strength:

- Doramectin
10.00
milligram(s)
/
1.00
millilitre(s)

Pharmaceutical form:

- Solution for injection

Withdrawal period by route of administration:

- Intramuscular use
 - Sheep
 - Meat and offal
70
day
 - Pig

- Meat and offal
77
day
- Subcutaneous use
 - Cattle
 - Meat and offal
70
day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

- QP54AA03

Legal status of supply:

- Veterinary medicinal product subject to veterinary prescription

Authorisation status:

- Valid

Authorised in:

- France

Available in:

- France

Package description:

- The product is supplied in 250 ml multi-dose Type II amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps.
- The product is supplied in 500 ml multi-dose Type II or Type III amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps.
- The product is supplied in 200 ml multi-dose Type II or Type III amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps.
- The product is supplied in 50 ml multi-dose Type II or Type III amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps.

Additional information

Entitlement type:

- Marketing Authorisation

Legal basis of product authorisation:

- Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

- Zoetis France

Marketing authorisation date:

- 9/07/2012

Manufacturing sites for batch release:

- Zoetis Manufacturing & Research Spain S.L.
- Zoetis Belgium SA

Responsible authority:

- French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

- FR/V/4335418 4/2012

Date of authorisation status change:

- 22/06/2016

Reference member state:

- Ireland

Procedure number:

- IE/V/0260/001

Concerned member states:

- Austria
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Estonia
- France
- Greece
- Hungary
- Latvia
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Spain

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Product information

Summary of Product Characteristics

English (PDF)

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French (PDF)

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Package Leaflet and Labelling

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